# PATIENT SAFETY
# April 2005

1: AIDS Alert. 2005 Mar;20(3):34-6.

Africa, India test sites for anti-HIV microbicide. Cellulose sulfate tested in high-risk women.

[No authors listed]

Phase III effectiveness clinical trials have begun for the potential anti-HIV microbicide cellulose sulfate (Ushercell), formerly called C31G, which already has demonstrated safety when used by women. If the trials go well, the product could be ready for approval by the FDA by 2010.

Publication Types:
Newspaper Article

PMID: 15789474 [PubMed - indexed for MEDLINE]

2: Altern Med Rev. 2005 Mar;10(1):36-41.

Hormone replacement with estradiol: conventional oral doses result in excessive exposure to estrone.

Friel PN, Hinchcliffe C, Wright JV.

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BACKGROUND: There is a lack of consensus about the safety of estrogen replacement therapy, especially with regard to its impact on a woman's risk for breast cancer. Elevated urinary or serum estrone and estradiol concentrations in postmenopausal women are associated with a moderately elevated risk of breast cancer. METHODS: Twenty-four-hour urinary steroid hormone profiles, including the measurement of estrone, estradiol, and estriol, were conducted for 35 postmenopausal women receiving oral estradiol at doses from 0.025-2.0 mg/day. RESULTS: Urinary excretion of estradiol exceeded premenopausal reference range values in women taking estradiol at doses greater than 0.5 mg/day. Urinary estrone excretion exceeded premenopausal reference range values in women taking estradiol doses of 0.25 mg/day or higher. Literature data indicate serum estrone concentrations also markedly exceed premenopausal reference ranges when estradiol is administered orally at a dose of 1 mg/day. CONCLUSIONS: The previously recommended oral dose of estradiol (1-2 mg/day) results in urinary excretion of estrone at values 5-10 times the upper limit of the reference range

for premenopausal women. Retrospective studies associating oral estradiol with increased risk of breast cancer may reflect overdose conditions. Based on current knowledge, a prudent dose ceiling for oral estradiol replacement therapy of 0.25 mg/day is proposed.

PMID: 15771561 [PubMed - indexed for MEDLINE]

3: Am J Clin Dermatol. 2005;6(2):89-92.

Microdermabrasion.

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Microdermabrasion is a simple, safe, office cosmetic procedure in which aluminum oxide crystals or other abrasive substances are blown onto the face, then vacuumed off, using a single handpiece. This procedure has rapidly become widely utilized for a variety of cosmetic objectives, including the improvement of photoaging, hyperpigmentation, acne, scars and stretch marks. Despite its widespread use, little is known about its actual mechanism of action. The few published studies suggest that patients and physicians alike report a mild benefit when microdermabrasion is utilized for photoaging. Histologic evaluation reveals little actual abrasion of the skin with the procedure, yet changes are seen in the dermis. Given the safety, simplicity and patient satisfaction associated with microdermabrasion, it is likely to remain a popular treatment.

PMID: 15799680 [PubMed - in process]

4: Am J Gastroenterol. 2005 Apr;100(4):817-20.

Insertability and safety of a shape-locking device for colonoscopy.

Rex DK, Khashab M, Raju GS, Pasricha J, Kozarek R.

Division of Gastroenterology/Hepatology, Indiana University Medical Center, Indianapolis, Indiana.

BACKGROUND: Loop formation during colonoscopy insertion results in patient pain and delays in advancement of the colonoscope tip. AIM: To assess the insertability and safety of a novel shape-locking guide (ShapeLock, USGI, San Clemente, CA) that resists looping during colonoscopy. RESULTS: In 54 patients, both a disposable and a partly reusable version of the ShapeLock received high scores (mean scores >9.0 on 1-10 scale) for ease of insertion, and ability to maneuver the colonoscope through the shape locked device. No significant trauma resulted from use of the device. CONCLUSION: A novel shape-locking device for colonoscopy can be readily and safely inserted into the colon and locked. The device warrants controlled evaluation to determine in which, if any cases, it may be useful for either experienced colonoscopists and/or those with less or minimal experience. (Am J Gastroenterol 2005;100:1-4).

PMID: 15784024 [PubMed - in process]

5: Am J Health Syst Pharm. 2005 Apr 1;62(7):726-31.

Patient-assistance programs: Assessment of and use by safety-net clinics.

Duke KS, Raube K, Lipton HL.

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PURPOSE: Safety-net clinics' use and assessment of patient-assistance programs (PAPs) were studied. METHODS: A multistate telephone survey was conducted on the basis of issues identified during 10 case-study interviews of safety-net clinics serving primarily uninsured and publicly insured patients. Interviewed were pharmacists and other staff taking primary responsibility for helping patients apply to PAPs. RESULTS: Of 339 survey candidates, 215 provided complete interviews (63% response rate). Ninety-three percent of the completed interviews were with clinics in California, Texas, and Florida. Forty percent of the clinics reported that at least 75% of their patients lacked drug insurance coverage. There was a significant positive relationship between a clinic's likelihood of using PAPs and the percentage of its patients lacking drug coverage. PAPs consumed 12 hours of pharmacist time per month and 99 hours of other staff time per month. Clinics most frequently cited program requirements changing without notice and unrealistic income-documentation rules as potential barriers to PAP use and indicated that consistent eligibility criteria and standardized application procedures were needed. CONCLUSION: A survey of safety-net clinics indicated that PAPs help fill a major gap in health insurance coverage but that consistent eligibility criteria and application procedures are needed.

PMID: 15790800 [PubMed - in process]

6: Am J Surg. 2005 Mar;189(3):264-7.

Special address to the Midwest Surgical Association on surgical outcome analysis and patient safety.

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PMID: 15792747 [PubMed - in process]

7: Anesthesiology. 2005 Apr;102(4):822-831.

Efficacy and Safety of Single and Repeated Administration of 1 Gram Intravenous Acetaminophen Injection (Paracetamol) for Pain Management after Major Orthopedic Surgery.

Sinatra RS, Jahr JS, Reynolds LW, Viscusi ER, Groudine SB, Payen-Champenois C.

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BACKGROUND:: Intravenous acetaminophen injection (paracetamol) is marketed in Europe for the management of acute pain. A repeated-dose, randomized, double-blind, placebo-controlled, three-parallel group study was performed to evaluate the analgesic efficacy and safety of intravenous acetaminophen as compared with its prodrug (propacetamol) and placebo. Propacetamol has been available in many European countries for more than 20 yr. METHODS:: After orthopedic surgery, patients reporting moderate to severe pain received either 1 g intravenous acetaminophen, 2 g propacetamol, or placebo at 6-h intervals over 24 h. Patients were allowed "rescue" intravenous patient-controlled analgesia morphine. Pain intensity, pain relief, and morphine use were measured at selected intervals. Safety was monitored through adverse event reporting, clinical examination, and laboratory testing. RESULTS:: One hundred fifty-one patients (intravenous acetaminophen: 49; propacetamol: 50; placebo: 52) received at least one dose of study medication. The intravenous acetaminophen and propacetamol groups differed significantly from the placebo group regarding pain relief from 15 min to 6 h ($P < 0.05$) and median time to morphine rescue (intravenous acetaminophen: 3 h; propacetamol: 2.6 h; placebo: 0.8 h). Intravenous acetaminophen and propacetamol significantly reduced morphine consumption over the 24-h period: The total morphine doses received over 24 h were 38.3 +/- 35.1 mg for intravenous acetaminophen, 40.8 +/- 30.2 mg for propacetamol, and 57. 4 +/- 52.3 mg for placebo, corresponding to decreases of -33% (19 mg) and -29% (17 mg) for intravenous acetaminophen and propacetamol, respectively. Drug-related adverse events were reported in 8.2%, 50% (most of them local), and 17.3% of patients treated with intravenous acetaminophen, propacetamol, and placebo, respectively. CONCLUSION:: Intravenous acetaminophen, 1 g, administered over a 24-h period in patients with moderate to severe pain after orthopedic surgery provided rapid and effective analgesia and was well tolerated.

PMID: 15791113 [PubMed - as supplied by publisher]

8: Ann Intern Med. 2005 Apr 5;142(7):532-46.

Summary for patients in:
Ann Intern Med. 2005 Apr 5;142(7):I55.

Meta-analysis: pharmacologic treatment of obesity.

Li Z, Maglione M, Tu W, Mojica W, Arterburn D, Shugarman LR, Hilton L, Suttorp M, Solomon V, Shekelle PG, Morton SC.

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BACKGROUND: In response to the increase in obesity, pharmacologic treatments for weight loss have become more numerous and more commonly used. PURPOSE: To assess the efficacy and safety of weight loss medications approved by the U.S. Food and Drug Administration and other medications that have been used for weight loss. DATA SOURCES: Electronic databases, experts in the field, and unpublished information. STUDY SELECTION: Up-to-date meta-analyses of sibutramine, phentermine, and diethylpropion were identified. The authors assessed in detail 50 studies of orlistat, 13 studies of fluoxetine, 5 studies of bupropion, 9 studies of topiramate, and 1 study each of sertraline and zonisamide. Meta-analysis was performed for all medications except sertraline, zonisamide, and fluoxetine, which are summarized narratively. DATA EXTRACTION: The authors abstracted information about study design, intervention, co-interventions, population, outcomes, and methodologic quality, as well as weight loss and adverse events from controlled trials of medication. DATA SYNTHESIS: All pooled weight loss values are reported relative to placebo. A meta-analysis of

sibutramine reported a mean difference in weight loss of 4.45 kg (95% CI, 3.62 to 5.29 kg) at 12 months. In the meta-analysis of orlistat, the estimate of the mean weight loss for orlistat-treated patients was 2.89 kg (CI, 2.27 to 3.51 kg) at 12 months. A recent meta-analysis of phentermine and diethylpropion reported pooled mean differences in weight loss at 6 months of 3.6 kg (CI, 0.6 to 6.0 kg) for phentermine-treated patients and 3.0 kg (CI, -1.6 to 11.5 kg) for diethylpropion-treated patients. Weight loss in fluoxetine studies ranged from 14.5 kg of weight lost to 0.4 kg of weight gained at 12 or more months. For bupropion, 2.77 kg (CI, 1.1 to 4.5 kg) of weight was lost at 6 to 12 months. Weight loss due to topiramate at 6 months was 6.5% (CI, 4.8% to 8.3%) of pretreatment weight. With one exception, long-term studies of health outcomes were lacking. Significant side effects that varied by drug were reported. LIMITATIONS: Publication bias may exist despite a comprehensive search and despite the lack of statistical evidence for the existence of bias. Evidence of heterogeneity was observed for all meta-analyses. CONCLUSIONS: Sibutramine, orlistat, phentermine, probably diethylpropion, bupropion, probably fluoxetine, and topiramate promote modest weight loss when given along with recommendations for diet. Sibutramine and orlistat are the 2 most-studied drugs.

Publication Types:
Meta-Analysis

PMID: 15809465 [PubMed - indexed for MEDLINE]

9: Ann Intern Med. 2005 Apr 5;142(7):490-6.

Comment in:
Ann Intern Med. 2005 Apr 5;142(7):583-5.

Summary for patients in:
Ann Intern Med. 2005 Apr 5;142(7):I48.

A randomized trial of diagnostic strategies after normal proximal vein ultrasonography for suspected deep venous thrombosis: D-dimer testing compared with repeated ultrasonography.

Kearon C, Ginsberg JS, Douketis J, Crowther MA, Turpie AG, Bates SM, Lee A, Brill-Edwards P, Finch T, Gent M.

McMaster University and the Henderson Research Centre, Hamilton, Ontario, Canada.

BACKGROUND: With suspected deep venous thrombosis and normal results on proximal vein ultrasonography, a negative d-dimer result may exclude thrombosis and a positive D-dimer result may be an indication for venography. OBJECTIVE: To evaluate and compare the safety of 2 diagnostic strategies for deep venous thrombosis. DESIGN: Randomized, multicenter trial. SETTING: Four university hospitals. PATIENTS: 810 outpatients with suspected deep venous thrombosis and negative results on proximal vein ultrasonography. INTERVENTIONS: Erythrocyte agglutination D-dimer testing followed by no further testing if the result was negative and venography if the result was positive (experimental) or ultrasonography repeated after 1 week in all patients (control). MEASUREMENTS: Symptomatic deep venous thrombosis diagnosed initially and symptomatic venous thromboembolism during 6 months of follow-up. RESULTS: Nineteen of 408 patients (4.7%) in the D-dimer group and 3 of 402 patients (0.7%) in the repeated ultrasonography group initially received a diagnosis of deep venous thrombosis ($P < 0.001$). During follow-up of patients without a diagnosis of deep venous thrombosis on initial testing, 8 patients (2.1% [95% CI, 0.9% to 4.0%]) in the D-dimer group and 5 patients (1.3% [CI, 0.4% to 2.9%]) in the repeated

ultrasonography group developed symptomatic venous thromboembolism (difference, 0.8 percentage point [CI, -1.1 to 2.9 percentage points]; P > 0.2). Venous thromboembolism occurred in 1.0% (CI, 0.2% to 2.8%) of those with a negative D-dimer result. LIMITATIONS: Seventy patients (8.6%) deviated from the diagnostic protocols, and 9 patients (1.1%) had inadequate follow-up. CONCLUSION: In outpatients with suspected deep venous thrombosis who initially had normal results on ultrasonography of the proximal veins, a strategy based on D-dimer testing followed by no further testing if the result was negative and venography if the result was positive had acceptable safety and did not differ from the safety of a strategy based on withholding anticoagulant therapy and routinely repeating ultrasonography after 1 week.

Publication Types:
- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

PMID: 15809460 [PubMed - indexed for MEDLINE]

10: AORN J. 2005 Feb;81(2):336-41; quiz 343-6.

Update on the National Patient Safety Goals--changes for 2005.

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Each year sice 2003, the Joint Commission on Accreditation of Healthcare Organizations has established National Patient Safety Goals for accredited health care organizations. The goals are developed to promote improvement in patient safety by helping health care organizations address specific safety concerns. This article discusses the current goals and highlights new information for 2005.

PMID: 15768544 [PubMed - in process]

11: Arch Intern Med. 2005 Mar 14;165(5):578-85.

Effect of nandrolone decanoate therapy on weight and lean body mass in HIV-infected women with weight loss: a randomized, double-blind, placebo-controlled, multicenter trial.

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BACKGROUND: Weight loss is associated with accelerated mortality and disease progression in patients with human immunodeficiency virus (HIV) infection. Although studies have examined a variety of anabolic therapies in HIV-infected men, the safety and efficacy of such treatments in women have not been adequately studied. METHODS: In this randomized, double-blind, placebo-controlled, multicenter, phase I/II study, 38 HIV-infected women with documented weight loss of 5% or greater in the preceding year or a body mass index of less than 20 kg/m(2) were randomized to receive nandrolone decanoate (100 mg) or an equivalent volume of placebo every other week by intramuscular

injection. Subjects received blinded treatment for 12 weeks, followed by open-label therapy for 12 weeks. Lean body mass and fat (bioelectrical impedance analysis) and weight were measured at baseline and at weeks 6, 12, 18, and 24. Biochemical assessments of safety (hematologic analyses, liver function tests, and sex hormone measurements) were performed at these same time points. Clinical signs and symptoms were monitored biweekly. RESULTS: Subjects randomized to receive nandrolone had significant increases in weight and lean body mass during blinded treatment (4.6 kg [9.0%] and 3.5 kg [8.6%], respectively; P<.001 vs baseline and placebo in each case). Fat mass did not change statistically significantly in either group. Although there were no statistically significant differences between groups in biochemical measures, the number of grade 3 or greater toxicities, or reports of virilizing effects, a full assessment of safety cannot be made in a trial of this size. CONCLUSION: Nandrolone decanoate therapy may prove to be generally safe and beneficial in reversing weight loss and lean tissue loss in women with HIV infection and other chronic catabolic diseases.

Publication Types:
- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

PMID: 15767536 [PubMed - indexed for MEDLINE]

12: Arch Intern Med. 2005 Mar 14;165(5):574-7.

Missed hypothyroidism diagnosis uncovered by linking laboratory and pharmacy data.

Schiff GD, Kim S, Krosnjar N, Wisniewski MF, Bult J, Fogelfeld L, McNutt RA.

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BACKGROUND: Although diagnostic errors are important, they have received less attention than medication errors. Timely follow-up of abnormal laboratory test results represents a critical aspect of the diagnostic process, and failures at this step are a cause of delayed or missed diagnosis, resulting in suboptimal clinical outcomes and malpractice litigation. We linked laboratory and pharmacy databases to (1) explore the potential for linking laboratory and pharmacy databases to uncover diagnostic errors, and (2) determine the frequency of failed follow-up of elevated levels of thyroid-stimulating hormone (TSH). METHODS: We downloaded TSH test results for 2 consecutive years from a laboratory database and linked this database with a pharmacy database to screen for patients with TSH levels of 20 mU/mL or higher who were not receiving levothyroxine. Patients with elevated TSH levels lacking prescriptions were followed up by telephone and record review. RESULTS: During the 2-year period, 982 (2.7%) of 36 760 unique patients tested for TSH level had elevated TSH levels. Of these patients, 177 (18.0%) had no recorded levothyroxine prescriptions. We attempted to contact 177 patients with high TSH levels who were not taking thyroid medications and reached 123 (69.5%). Of the 123 patients we were able to reach, 12 in 2000 and 11 in 2001 were unaware of their abnormal test results or a diagnosis of hypothyroidism, representing 2.3% of 982 patients with elevated TSH levels. We were unable to reach another 54 patients (5.5% of the total number of patients with elevated TSH levels) by either telephone or mail. CONCLUSIONS: By linking laboratory and pharmacy databases, we uncovered patients who did not undergo follow-up for abnormal TSH results. Conservatively, there was no follow-up for abnormal TSH results in more than 2% of patients, and another 5% of patients were lost to follow-up and possibly unaware of their

results. Uncovering patients with missed diagnosis illustrates a potential use of linking laboratory and pharmacy databases to identify vulnerabilities in the care system and improve patient safety.

PMID: 15767535 [PubMed - indexed for MEDLINE]

13: Cancer Invest. 2005;23(1):13-8.

Phase II study of weekly low-dose paclitaxel for relapsed and refractory non-Hodgkin's lymphoma: a Wisconsin Oncology Network Study.

Kahl BS, Bailey HH, Smith EP, Turman N, Smith J, Werndli J, Williams EC, Longo WL, Kim KM, McGovern J, Jumonville A.

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This study was performed to determine the clinical activity and safety of weekly low-dose paclitaxel (90 mg/m2) given as a 1-hour infusion in patients with relapsed and refractory non-Hodgkin's lymphoma (NHL). Thirty patients were treated on a phase II protocol conducted at the University of Wisconsin Comprehensive Cancer Center and within the Wisconsin Oncology Network (WON). A cycle of therapy was defined as paclitaxel at 90 mg/m2 weekly for 6 consecutive weeks followed by a 2-week rest period. Cycles were repeated as long as there was no disease progression or unacceptable toxicity. In general, the patients were heavily pretreated with a median of 4 prior therapies (range 2-11), and 73% were refractory to the most recent systemic therapy. The median age was 70 (range 44-97). All NHL histological subtypes were eligible. Of the 30 eligible patients enrolled, 26 were evaluable for response and 28 for toxicity. The overall response rate was 23% (95% confidence interval (CI) 9.0-43.7%). One patient had a complete response, and 5 patients had partial responses. The median response duration was 3.2 months (range 1.4-11.8 months). The median event-free survival was 1.9 months. The major toxicity was neuropathy. Despite the limited marrow reserve in this patient population, myelosuppression was minimal. Paclitaxel given in this dose and schedule has modest activity in previously treated non-Hodgkin's lymphoma. The response rate appears similar to other reports using different doses and schedules. Myelosuppression appears less with this schedule than with other schedules.

PMID: 15779863 [PubMed - in process]

14: Cardiovasc Pathol. 2005 Mar-Apr;14(2):47-8.

The academic autopsy: A patient safety issue.

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Publication Types:
Editorial

PMID: 15780795 [PubMed - in process]

15: Clin Infect Dis. 2005 Apr 1;40(7):962-7. Epub 2005 Mar 3.

Multistate outbreak of Listeria monocytogenes infection linked to delicatessen turkey meat.

Olsen SJ, Patrick M, Hunter SB, Reddy V, Kornstein L, MacKenzie WR, Lane K, Bidol S, Stoltman GA, Frye DM, Lee I, Hurd S, Jones TF, LaPorte TN, Dewitt W, Graves L, Wiedmann M, Schoonmaker-Bopp DJ, Huang AJ, Vincent C, Bugenhagen A, Corby J, Carloni ER, Holcomb ME, Woron RF, Zansky SM, Dowdle G, Smith F, Ahrabi-Fard S, Ong AR, Tucker N, Hynes NA, Mead P.

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BACKGROUND: Despite a decreasing incidence of listeriosis in the United States, molecular subtyping has increased the number of recognized outbreaks. In September 2000, the New York City Department of Health identified a cluster of infections caused by Listeria monocytogenes isolates with identical molecular subtypes by pulsed-field gel electrophoresis (PFGE) and ribotyping. METHODS: To determine the magnitude of the outbreak and identify risk factors for infection, we notified state health departments and conducted a case-control study. A case was defined as a patient or mother-infant pair infected with Listeria monocytogenes whose isolate yielded the outbreak PFGE pattern. Controls were patients infected with Listeria monocytogenes whose isolate yielded a different PFGE pattern. Patients were asked about food and drink consumed during the 30 days before the onset of illness. RESULTS: Between May and December 2000, there were 30 clinical isolates of Listeria monocytogenes with identical PFGE patterns identified in 11 US states. Cases of infection caused by these isolates were associated with 4 deaths and 3 miscarriages. A case-control study implicated sliced processed turkey from a delicatessen (Mantel-Haenszel odds ratio, 8.0; 95% confidence interval, 1.2-43.3). A traceback investigation identified a single processing plant as the likely source of the outbreak, and the company voluntarily recalled 16 million pounds of processed meat. The same plant had been identified in a Listeria contamination event that had occurred more than a decade previously. CONCLUSIONS: Prevention of persistent L. monocytogenes contamination in food processing plants presents a critical challenge to food safety professionals.

PMID: 15824987 [PubMed - in process]

16: Health Care Manage Rev. 2005 Jan-Mar;30(1):1.

Patient safety culture.

Pinkerton S.

Publication Types:
Editorial

PMID: 15773247 [PubMed - in process]

17: Health Manag Technol. 2005 Mar;26(3):20, 22-3.

Lab link to patient safety.

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PMID: 15786947 [PubMed - in process]

18: Heart. 2005 Mar 17; [Epub ahead of print]

Time to treatment and the impact of a physician on pre-hospital management of acute ST elevation myocardial infarction: insights from the ASSENT-3 PLUS trial.

Welsh RC, Chang WC, Goldstein P, Adgey J, Granger CB, Verheugt FW, Wallentin L, Van de Werf F, Armstrong PW.

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Objectives: ASSENT-3 PLUS a large (n=1639) contemporary multi-centered international trial of pre- hospital fibrinolysis provided an opportunity to assess the impact of variation in pre-hospital care across distinct health care environments. Our objectives were to assess: 1) predictors of time to treatment, 2) whether components of time to treatment vary across countries, and 3) the impact of physician presence pre- hospital on time to treatment, adherence to protocol and clinical events. Methods: Patient characteristics associated with early treatment (</=2hrs.), comparison of international variation in time to treatment and components of delay was undertaken. Trial specific patient data were linked with site-specific survey responses. Results: Younger age, slower HR, lower systolic BP, and prior PCI were associated with early treatment. Country of origin accounted for the largest proportion of variation in time. Inter-country heterogeneity was demonstrated in components of elapsed time to treatment. Physicians in the pre-hospital setting enrolled 63.8% of patients. The presence of a physician was associated with greater adherence to protocol mandated therapies and procedures, but delay in time to treatment (120 vs. 108 min, p<. 001). Conclusion: Country of enrollment accounted for the largest proportion of variation in time to treatment and inter-country heterogeneity modulated components of delay. The efficacy and safety of pre-hospital fibrinolysis was not influenced by the presence of a physician. These data, acquired in diverse health care environments, provide new understanding into the components of pre-hospital treatment delay and the opportunities to further reduce time to fibrinolysis for patients with STEMI.

PMID: 15774607 [PubMed - as supplied by publisher]

19: HIV Med. 2005 Mar;6(2):107-13.

Comparison of gastrointestinal tolerability and patient preference for treatment with the 625 mg and 250 mg nelfinavir tablet formulations.

Johnson M, Nieto-Cisneros L, Horban A, Arasteh K, Gonzalez-Garcia J, Artigas JG, Clotet B, Danise A, Landman R, Proll S, Snowden W, Foreman R, Smith P.

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OBJECTIVES: To compare gastrointestinal (GI) tolerability and patient preference for the new 625 mg formulation of nelfinavir (NFV) and the marketed 250 mg tablets (Viracept) in HIV-1-infected patients. METHODS: Virologically controlled

patients (n=126) treated with a nelfinavir (NFV) 250 mg-containing regimen for > or =8 weeks completed a stool diary for 14 days to assess baseline bowel function. After switching to the NFV 625 mg formulation [1250 mg twice a day (bid)] for 28 days, patients continued their stool diaries and at study completion answered a questionnaire regarding formulation preferences. RESULTS: The incidence and mean weekly duration of GI upset over a 2-week period were lower with NFV 625 mg than with NFV 250 mg (79.8% vs. 84.9% of patients and 2.1 vs. 3.0 days, respectively). Fewer patients experienced moderate or severe diarrhoea with NFV 625 mg (6.5% vs. 11.1%), and the incidence of investigator-assessed diarrhoea also decreased with NFV 625 mg. Importantly, there was a significant improvement overall in the incidence of diarrhoea (any grade) when patients switched to NFV 625 mg [38 of 124 (31%) improving, 69 of 124 (56%) stable and 17 of 124 (14%) worsening on NFV 625 mg; P<0.01]. At study completion, most patients expressed a preference to continue treatment with NFV 625 mg [112 of 122 (91.8%); P<0.0001], with only one patient (0.8%) preferring to resume treatment with NFV 250 mg. The new formulation was well tolerated with no new safety concerns. CONCLUSIONS: The new NFV 625 mg formulation is better tolerated and preferred by patients switching from NFV 250 mg tablets. By reducing the daily pill count and improving GI tolerability, the NFV 625 mg formulation may enhance patient adherence to NFV-containing antiretroviral regimens and thus potentially improve virological outcomes.

PMID: 15807716 [PubMed - in process]

20: Home Healthc Nurse. 2005 Apr;23(4):243-253.

MEDICATION SAFETY: Look-Alike/Sound-Alike Drugs in Home Care.

Friedman MM.

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A new Joint Commission on Accreditation of Healthcare Organizations National Patient Safety Goal (NPSG) for 2005 is related to look-alike/sound-alike medications. This article reviews this new goal and what actions home care and hospice organizations need to undertake to meet the intent of this new requirement and provides insightful home care and hospice adaptations to the NPSG's general goals. Even if an agency is not Joint Commission-accredited, this information should be integrated into policies, procedures, and clinician education to avoid dangerous and costly medication errors.

PMID: 15824614 [PubMed - as supplied by publisher]

21: Hosp Case Manag. 2005 Apr;13(4):1-2.

Patient safety alert. Keystone project yields results in six months.

[No authors listed]

PMID: 15794297 [PubMed - in process]

22: Hosp Health Netw. 2005 Feb;79(2):30-1.

Regulation. In the safety zone.

Manos D.

Publication Types:
News

PMID: 15770904 [PubMed - indexed for MEDLINE]

23: Int J Qual Health Care. 2005 Apr;17(2):93-4.

Beyond Babel: prospects for a universal patient safety taxonomy.

Weingart SN.

Center for Patient Safety, Dana-Farber Cancer Institute, and Harvard Medical School, Boston, MA, USA.

PMID: 15772256 [PubMed - in process]

24: J Clin Nurs. 2005 Apr;14(4):435-43.
Overcoming the barriers to patient-centred care: time, tools and training.

West E, Barron DN, Reeves R.

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west e, barron dn & reeves r (2005) Journal of Clinical Nursing14, 435-443 Overcoming the barriers to patient-centred care: time, tools and trainingAims and objectives. To investigate whether nurses experience barriers to delivering high quality care in areas that are of particular concern to patients and to describe which aspects of care are most affected when nurses lack the required resources, such as time, tools and training to do their job. Background. Patient surveys conducted in the National Health Service of the United Kingdom tend to show there is variation in the extent to which they are satisfied with care in a number of important areas, such as physical comfort, emotional support and the coordination of care. Design. A sample of nurses working in 20 acute London hospitals was asked to complete a postal questionnaire based on a prototype employee survey developed in the United States and adapted by the authors for use in the United Kingdom. Method. Staff in the human resources departments of participating hospitals mailed the questionnaires to nurses' home addresses. After two reminders, 2880 (out of 6160) useable responses were returned, giving a response rate of 47%. Results. Nurses are aware that there are deficits in standards of care in areas that are particularly important to patients. The majority feel overworked (64%) and report that they do not have enough time to perform essential nursing tasks, such as addressing patients' anxieties, fears and concerns and giving patients and relatives information. Their work is often made more difficult by the lack of staff, space, equipment and cleanliness. They are often unable to control noise and temperature in clinical areas. Nurses in acute London hospitals are subject to high levels of aggressive behaviour, mainly from patients and their relatives, but also from other members of staff. More positively, high proportions of the nurses in our survey expressed the desire for further training, particularly in social and interpersonal aspects of care. Relevance to clinical practice. This paper goes beyond reporting problems with the quality and safety of care to try to understand why patients do not always receive optimum care in areas that are important to them. In many cases

nurses lack the time, tools and training to deliver high quality care in acute

25: J Perinat Neonatal Nurs. 2005 Jan-Mar;19(1):15-23.

Improving perinatal and neonatal patient safety: The AHRQ patient safety indicators.

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This study reviews the development and implementation of the Agency for Healthcare Research and Quality (AHRQ) patient safety indicators (PSIs). The genesis of the use of administrative data as a tool to combat safety problems is presented, and how indicators were constructed using various administrative codes. Examples of how the PSIs are being used to identify potential safety problems within the general population are presented, with a special emphasis on how these are being used within the perinatal and neonatal arena to understand current issues within that subpopulation. Results from studies within the general population and targeted at perinatal and neonatal patients are presented. Finally, suggestions are discussed for clinicians to use the AHRQ PSIs as one of their early warning tools for potential safety-related problems.

PMID: 15796421 [PubMed - in process]

26: J Trauma. 2005 Apr;58(4):731-9.

Evaluation of the applicability, efficacy, and safety of a thromboembolic event prophylaxis guideline designed for quality improvement of the traumatically injured patient.

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BACKGROUND:: Thromboembolic events (TE) such as deep venous thrombosis (DVT) and pulmonary embolism (PE) are common after trauma. Our Trauma Practice Management Committee developed an evidence-based DVT/PE prophylaxis guideline using a modified Delphi approach to standardize care and reduce TE rates. Our objective was to evaluate the applicability, efficacy, and safety of this guideline in the traumatized patient, especially those admitted first to the intensive care unit (ICU). METHODS:: We developed a risk-stratified DVT/PE prophylaxis guideline incorporating specific injuries, pertinent history, and physiologic parameters, favoring aggressive therapy in those at highest risk of dying from a PE. We prospectively collected data using this guideline in all patients admitted to the trauma or orthopedic-trauma services that were expected to stay for more than 48 hours (March-December 2003). Comparison was made with historical controls. Data collected included DVT, PE, prophylaxis level chosen, inferior vena cava filters, admission service and location, TRISS scores, length of stay, outcomes, adverse events, and specific risk factors. RESULTS:: TE rates after

implementation of the guideline were lower than historical controls for all patients (1.9% vs. 1.0%, p = 0.059) and for patients admitted first to the ICU (6.3% vs. 2%, p = 0.018). Completed sheets were collected for 46% of the targeted population. No bleeding events caused by guideline anticoagulation were noted, and one death occurred after inferior vena cava filter placement. Nine of the 12 TEs in the treatment group were in patients with spine or closed-head injury, delaying chemical prophylaxis. CONCLUSION:: Form-based, risk-adjusted prophylaxis against TE leads to lower TE rates in a general and orthopedic ICU trauma population. Protocol compliance should be enforced.

PMID: 15824649 [PubMed - in process]

27: JAMA. 2005 Mar 16;293(11):1359-66.

Error reporting and disclosure systems: views from hospital leaders.

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CONTEXT: The Institute of Medicine has recommended establishing mandatory error reporting systems for hospitals and other health settings. OBJECTIVE: To examine the opinions and experiences of hospital leaders with state reporting systems. DESIGN AND SETTING: Survey of chief executive and chief operating officers (CEOs/COOs) from randomly selected hospitals in 2 states with mandatory reporting and public disclosure, 2 states with mandatory reporting without public disclosure, and 2 states without mandatory systems in 2002-2003. MAIN OUTCOME MEASURES: Perceptions of the effects of mandatory systems on error reporting, likelihood of lawsuits, and overall patient safety; attitudes regarding release of incident reports to the public; and likelihood of reporting incidents to the state or to the affected patient based on hypothetical clinical vignettes that varied the type and severity of patient injury. RESULTS: Responses were received from 203 of 320 hospitals (response rate = 63%). Most CEOs/COOs thought that a mandatory, nonconfidential system would discourage reporting of patient safety incidents to their hospital's own internal reporting system (69%) and encourage lawsuits (79%) while having no effect or a negative effect on patient safety (73%). More than 80% felt that the names of both the hospital and the involved professionals should be kept confidential, although respondents from states with mandatory public disclosure systems were more willing than respondents from the other states to release the hospital name (22% vs 4%-6%, P = .005). Based on the vignettes, more than 90% of hospital leaders said their hospital would report incidents involving serious injury to the state, but far fewer would report moderate or minor injuries, even when the incident was of sufficient consequence that they would tell the affected patient or family. CONCLUSIONS: Most hospital leaders expressed substantial concerns about the impact of mandatory, nonconfidential reporting systems on hospital internal reporting, lawsuits, and overall patient safety. While hospital leaders generally favor disclosure of patient safety incidents to involved patients, fewer would disclose incidents involving moderate or minor injury to state reporting systems.

PMID: 15769969 [PubMed - indexed for MEDLINE]

28: Jt Comm J Qual Patient Saf. 2005 Feb;31(2):63-5, 61.

Introduction: Communicating critical test results.

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The need for improving the timeliness of the communication of critical test results is reflected in a Joint Commission National Patient Safety Goal and is the basis for this special issue of the Journal.

PMID: 15791764 [PubMed - in process]

29: Mayo Clin Proc. 2005 Apr;80(4):541-5.

Ischemic stroke associated with use of an ephedra-free dietary supplement containing synephrine.

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In response to concerns regarding the safety of ephedra-containing dietary supplements, manufacturers have marketed "ephedra-free" products. Many of these contain synephrine, a sympathomimetic amine from the plant Citrus aurantium. Synephrine is structurally similar to ephedrine and has vasoconstrictor properties. We describe a 38-year-old patient with ischemic stroke associated with an ephedra-free dietary supplement containing synephrine and caffeine. The patient presented with memory loss and unsteady gait after taking 1 or 2 capsules per day of a dietary supplement (Stacker 2 Ephedra-Free) for 1 week. He had no notable medical history or major atherosclerotic risk factors and took no other medications. Physical examination showed a mildly ataxic gait and substantial Impairment of both concentration and memory. Computed tomography and magnetic resonance Imaging of the brain showed subacute infarctions in the left thalamus and left cerebellum in the distribution of the vertebrobasilar circulation. Other causes of ischemic stroke were evaluated, and findings were unremarkable; a vasospastic origin was considered most likely. The patient was discharged with nearly complete resolution of symptoms. Synephrine, a sympathomimetic amine related to ephedrine, may be associated with Ischemic stroke. Consumers and clinicians need to be Informed about the potential risks of ephedra-free products.

PMID: 15819293 [PubMed - in process]

30: Mayo Clin Proc. 2005 Apr;80(4):470-9.

Evaluation of the comparative efficacy of etoricoxib and ibuprofen for treatment of patients with osteoarthritis: A randomized, double-blind, placebo-controlled trial.

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OBJECTIVE: To directly compare the efficacy and safety of etoricoxib, 30 mg once daily, ibuprofen, 800 mg 3 times daily, and placebo for treatment of

osteoarthritis (OA) of the hip and knee. PATIENTS AND METHODS: A randomized, double-blind, placebo-controlled trial of patients with OA of the knee or hip was performed between February 2003 and November 2003 in 61 medical centers in the United States. Qualified patients aged 40 to 89 years were randomized to receive placebo, etoricoxib, 30 mg once daily, or ibuprofen, 800 mg 3 times daily, for 12 weeks. Primary efficacy end points Included the Western Ontario and McMaster Universities Osteoarthritis Index pain and physical function subscales and Patient Global Assessment of Disease Status. Response to treatment was assessed by the time-weighted average change from baseline over 12 weeks. RESULTS: In 528 patients, baseline values for the 3 primary end points ranged from 67.78 to 72.60 mm (0-100 mm visual analog scale). Near-maximal efficacy was achieved by week 2 with both active treatments and sustained over the course of the trial. During the 12-week period, least squares mean changes in the primary end points (Western Ontario and McMaster Universities Osteoarthritis Index and Patient Global Assessment of Disease Status subscales) ranged from -16.53 to -13.55 mm, -27.89 to -23.68 mm, and -26.53 to -22.97 mm in the placebo, etoricoxib, and Ibuprofen groups, respectively. Both etoricoxib and ibuprofen were more effective (P<.001) than placebo for all primary end points. Etoricoxib and ibuprofen treatment responses for the primary end points were determined to be comparable with use of prespecified comparability criteria. Results for all other efficacy end points were consistent with responses observed for the primary end points. Etoricoxib and ibuprofen generally were well tolerated. CONCLUSION: For patients with OA, treatment with etoricoxib, 30 mg/d, is well tolerated and provides sustained clinical effectiveness that is superior to placebo and comparable to ibuprofen, 2400 mg/d.

PMID: 15819283 [PubMed - in process]

31: N Engl J Med. 2005 Mar 31;352(13):1283-5.

Raising the safety bar--the FDA's coxib meeting.

Okie S.

PMID: 15800221 [PubMed - indexed for MEDLINE]

32: Nurs Adm Q. 2005 Jan-Mar;29(1):97-101.

Patient and nurse safety: how information technology makes a difference.

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The Institute of Medicine's landmark report asserted medical error is seldom the fault of individuals, but the result of faulty healthcare policy/procedure systems. Numerous studies have shown that information technology can shore up weak systems. For nursing, information technology plays a key role in protecting patients by eliminating nursing mistakes and protecting nurses by reducing their negative exposure. However, managing information technology is a function of managing the people who use it. This article examines critical issues that impact patient and nurse safety, both physical and professional. It discusses the importance of eliminating the culture of blame, the requirements of process change, how to implement technology in harmony with the organization and the significance of vision.

PMID: 15779711 [PubMed - in process]

32: Nurs Adm Q. 2005 Jan-Mar;29(1):88-96.

Patient safety: a priority in the US Department of Health and Human Services.

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This descriptive article provides information about some of the major patient safety initiatives within the operating and staff divisions of the US Department of Health and Human Services. The research for this article was done using the internet. Many health professionals and consumers turn first to the internet while researching a disease or new diagnosis, or while seeking general health information. It is important for nurse administrators to know what resources are readily available to help them implement regulatory requirements, what voluntary programs exist for reporting problems with medical products, what resources are available for consumers to make informed health choices, and where they can get information about specific Department of Health and Human Services programs.

PMID: 15779710 [PubMed - in process]

33: Nurs Adm Q. 2005 Jan-Mar;29(1):78-87.

Intravenous medication safety system averts high-risk medication errors and provides actionable data.

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A major responsibility of nursing leaders is to implement systems and policies to improve patient and staff safety, avoid medication errors, and most importantly safeguard patients against harm. In the medication use process, the nurse at the bedside is the most vulnerable, and intravenous (i.v.) drug administration often results in the most serious medication error outcomes. At a 675-bed, tertiary-care "Magnet Hospital System," nurses played a key role in a multidisciplinary process that led to successful implementation of a computerized i.v. medication safety system. Software customization, staff training and product set-up were completed in approximately 2 months; 685 devices were installed in 3 hospitals within 12 hours. Nursing acceptance is excellent, and implementation of the system is thought to enhance nursing retention and recruitment. Preliminary data indicate an estimated 849 programming changes ("near misses") annually, ie, potential infusion errors averted by the i.v. medication safety system. A chronogram created from safety data demonstrates that most infusion error warnings occurred between 3:00 PM and 9:00 PM, with an unexpected peak at 6:00 PM. Implementation of the i.v. medication safety system has prevented potentially serious infusion errors and has provided previously unavailable, actionable continuous quality improvement data for best practice improvements.

PMID: 15779709 [PubMed - in process]

34: Nurs Adm Q. 2005 Jan-Mar;29(1):72-7.

Using information to empower nurse managers to become champions for patient safety.

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There is no longer any question about the risks to patients safety that exist in the hospital. Hospitals are macrosystems that are built upon many interrelated microsystems. Most patient care and hence most errors that directly affect the care outcomes and negatively impact patient safety occur at the microsystem unit level, which is the same level that many improvements to patient safety occur. Patient Safety Net (PSN) is an on-line occurrence reporting tool being used by University HealthSystem Consortium (UHC) member hospitals to report medical events and improve care. As PSN became progressively integrated into the daily operations of these UHC members isolated anecdotes began to surface about how unit nurse managers were able to implement rapid and effective patient safety improvements at the microsystem level on the basis of data received through PSN, without involving performance and safety committees mechanisms. This article highlights the survey performed to validate these improvement anecdotes.

PMID: 15779708 [PubMed - in process]

35: Nurs Adm Q. 2005 Jan-Mar;29(1):63-71.

A business case for patient care ergonomic interventions.

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This article provides a framework for a business case for patient ergonomic programs that accentuates the financial gains to be realized from such programs as compared to meeting safety requirements. An introduction is made to such commonly used measures as payback period, net present value analysis and internal rate of return. Financial measures on a successful patient handling project in the Veterans Health Administration are outlined and policy implications discussed.

PMID: 15779707 [PubMed - in process]

36: Nurs Adm Q. 2005 Jan-Mar;29(1):57-62.

Designing and implementing a close call reporting system.

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Medical errors and adverse events related to medication errors have received press coverage over the past 3 years. Nursing leaders have by necessity and duty become leaders in the field of patient safety. Defining and reporting errors become critical when analysis of errors relies on adequate and accurate

reporting of errors. The next step towards a culture of safety is to avoid "blaming" employees, establishing trust and instituting a close call/near miss reporting system. By encouraging all staff to identify close calls you raise the level of awareness of employees for maintaining a safe patient care environment. Nursing leaders need to guide staff in identifying and reporting close calls through the development and implementation of a transparent reporting system involving recognition and rewarding staff.

PMID: 15779706 [PubMed - in process]

37: Nurs Adm Q. 2005 Jan-Mar;29(1):45-56.

An innovative model for restraint use at the Philadelphia Veterans Affairs Medical Center.

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In this article, Quality Management Specialists at the Philadelphia Veterans Affairs Medical Center describe an innovative model for restraint use designed to ensure patient safety. They discuss the impetus of the model, its evolution, and purposes. The model provides alternatives to restraint use, education to staff, patients, and families, and electronic tools to monitor restraint usage. Descriptive statistics and analyses of outcomes generated from the electronic tools are presented to demonstrate the utility and value of the model. Future directions for the use of the model and data generated through the electronic record are highlighted.

PMID: 15779705 [PubMed - in process]

38: Nurs Adm Q. 2005 Jan-Mar;29(1):39-44.

Nurse's role in tracking adverse drug events: the impact of provider order entry.

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Adverse drug events (ADE), or injuries caused by drug therapy, are a frequent and serious problem in hospitalized patients. Monitoring, preventing, and treating ADEs is an important patient safety function. Nurses play a significant role in this function, because their data is a unique and important indicator of ADEs and because they are the final point of medication administration. New provider order entry systems with electronic medical records have been viewed as an effective innovation and solution to high rates of ADEs. These systems increase legibility of drug orders, provide decision support, and increase access to the medical record. However, they may not interface with nursing processes effectively. This study reports the experience of a team conducting an ADE surveillance study in a Veterans Health Administration setting where extensive computerized innovations are in place. Lessons learned regarding the integration of nursing work processes with the computerized setting are described. Three areas of concern are highlighted: decreased access to nursing narratives, lack of decision support for medication administration, and failure

to code nursing data. Each of these is discussed in terms of relevance to patient safety and the design of information systems.

PMID: 15779704 [PubMed - in process]

39: Nurs Adm Q. 2005 Jan-Mar;29(1):32-8.

Evolution of BCMA within the Department of Veterans Affairs.

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The Department of Veterans Affairs Medical Center implemented Bar Code Medication Administration (BCMA) between 1999 and 2000 in 161 Medical Centers or Health Systems. BCMA has had a major impact on inpatient licensed nursing staff. Nurses have moved from manual to electronic medication documentation, increasing the complexity of medication administration. There has been acceptance of BCMA by the nurses who are able to see the positive benefits and patient safety aspects. A marked decrease in medication administration errors is a result of implementing BCMA.

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40: Nurs Adm Q. 2005 Jan-Mar;29(1):1-2.

Patient and staff safety.

Brown BJ.

Publication Types:
Editorial

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41: Nurs BC. 2005 Feb;37(1):37.
Patient safety and duty to report.

Brunke L.

PMID: 15790284 [PubMed - in process]

42: Nurs Econ. 2005 Jan-Feb;23(1):42-5.

Implementing a patient safety alert system.

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PMID: 15768786 [PubMed - in process]

underlying individual and organizational values and assumptions in health care.

PMID: 15795018 [PubMed - in process]

43: Qual Saf Health Care. 2005 Apr;14(2):135-9.

Implementing a national strategy for patient safety: lessons from the National Health Service in England.

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Improving patient safety has become a core issue for many modern healthcare systems. However, knowledge of the best ways for government initiated efforts to improve patient safety is still evolving, although there is considerable commonality in the challenges faced by countries. Actions to improve patient safety must operate at multiple levels of the healthcare system simultaneously. Using the example of the NHS in England, this article highlights the importance of a strategic analysis of the policy process and the prevailing policy context in the design of the national patient safety strategy. The paper identifies a range of policy "levers" (forces for change) that can be used to support the implementation of the national safety initiative and, in particular, discusses the strengths and limitations of the "business case" approach that has attracted recent interest. The paper offers insights into the implementation of national patient safety goals that should provide learning for other countries.

PMID: 15805460 [PubMed - in process]

44: Qual Saf Health Care. 2005 Apr;14(2):130-4.

"Going solid": a model of system dynamics and consequences for patient safety.

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Rather than being a static property of hospitals and other healthcare facilities, safety is dynamic and often on short time scales. In the past most healthcare delivery systems were loosely coupled-that is, activities and conditions in one part of the system had only limited effect on those elsewhere. Loose coupling allowed the system to buffer many conditions such as short term surges in demand. Modern management techniques and information systems have allowed facilities to reduce inefficiencies in operation. One side effect is the loss of buffers that previously accommodated demand surges. As a result, situations occur in which activities in one area of the hospital become critically dependent on seemingly insignificant events in seemingly distant areas. This tight coupling condition is called "going solid". Rasmussen's dynamic model of risk and safety can be used to formulate a model of patient safety dynamics that includes "going solid" and its consequences. Because the model addresses the dynamic aspects of safety, it is particularly suited to understanding current conditions in modern healthcare delivery and the way these conditions may lead to accidents.

PMID: 15805459 [PubMed - in process]

45: Qual Saf Health Care. 2005 Apr;14(2):113-6.

# Do split-side rails present an increased risk to patient safety?

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BACKGROUND: Concerns have been raised about the safety of split-side bed rails for patients in the UK. OBJECTIVES: To investigate whether split-side rails were more likely to be associated with entrapment and injury of patients than other bed rail types. To establish whether there was a difference in the site of injury caused by different bed rail types and whether the outcome of the injury (death versus survival) varied by bedrail type. METHODS: A search of the USA Food and Drug Administration MAUDE database was carried out. The reports were screened using rigorous inclusion/exclusion criteria and then coded for rail type, incident outcome, and area of body involved. RESULTS: Split-side rail incidents only accounted for 5% of the reports and were more likely to involve the chest or pelvis. Although the biggest overall risk by rail type cannot be determined from these data, the severity of the outcome changed with the equipment type. Incidents involving half rails were more likely to be associated with head, neck, or face entrapments and were also more likely than other bed rail types to result in death. DISCUSSION: Split-side rail entrapments were not a common occurrence. However, our findings suggest that bed rails are associated with some level of risk of entrapment that potentially could result in death. Healthcare providers should therefore ensure that they follow the guidelines for risk assessment and rail use from the MHRA and other professional bodies so that the cultural norm in the UK continues to be "opt in", where no bed rails are used unless indicated by a documented clinical assessment.

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